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TOPICAL HAZARD EVALUATION PROGRAM OF CANDIDATE INSECT
REPELLENT A13-70957. (U) ARMY ENVIRONMENTAL HYGIENE
AGENCY ABERDEEN PROVING GROUND MD R D RUSSELL

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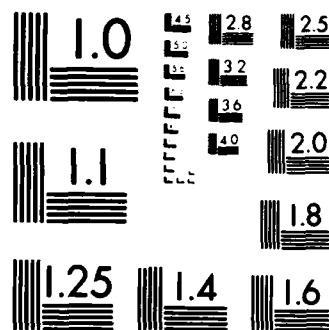
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**UNITED STATES ARMY
ENVIRONMENTAL HYGIENE
AGENCY**

ABERDEEN PROVING GROUND, MD 21010-5422

TOPICAL HAZARD EVALUATION PROGRAM
OF
CANDIDATE INSECT REPELLENT AI3-70957-Ga
US DEPARTMENT OF AGRICULTURE PROPRIETARY CHEMICAL
STUDY NO. 75-51-0517-85
AUGUST - SEPTEMBER 1984

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REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY CPT Russell/slw/AUTOVON
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY 584-3980
ABERDEEN PROVING GROUND, MARYLAND 21010-5422

HSHB-OT/WP

16 JAN 1985

SUBJECT: Topical Hazard Evaluation Program of Candidate Insect Repellent
AI3-70957-Ga, US Department of Agriculture Proprietary Chemical,
Study No. 75-51-0517-85, August - September 1984

Executive Secretary
Armed Forces Pest Management Board
Forest Glen Section, WRAMC
Washington, DC 20307

EXECUTIVE SUMMARY

The purpose, essential findings, and major recommendations of the enclosed report follow:

a. Purpose. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellent AI3-70957-Ga by means of laboratory animal studies using New Zealand White rabbits.

b. Essential Findings. Subject chemical produced moderate to severe primary irritation of intact skin and skin surrounding an abrasion.

c. Major Recommendation. Recommend that chemical AI3-70957-Ga be disapproved for further testing as a candidate insect repellent as described in the Toxicology Division Topical Hazard Evaluation Program Procedural Guide (reference paragraph 2, this report).

FOR THE COMMANDER:

Encl

JOEL C. GAYDOS
Colonel, MC
Director, Occupational and
Environmental Health

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HQDA(DASG-PSP) (wo/encl)
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USDA, ARS (Dr. Terrence McGovern) (w/encl)
USDA, ARS-Southern Region (3 cy) (w/encl)
Cdr, USAMRDC (SGRD-DPM/LTC Reinert) (wo/encl)

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| 4. TITLE (and Subtitle) Topical Hazard Evaluation Program of Candidate Insect Repellent, AI3-70957-Ga, US Department of Agriculture Proprietary Chemicals, Study No. 75-51-0517-84, August 1984 - September 1984 | | 5. TYPE OF REPORT & PERIOD COVERED Final, August 1984 - September 1984 |
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| 20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Preliminary hazard evaluation of subject candidate insect repellent was performed by means of laboratory animal studies using New Zealand white rabbits. Chemical AI3-70957-Ga produced moderate to severe primary skin irritation of the intact skin and the skin surrounding an abrasion. | | |

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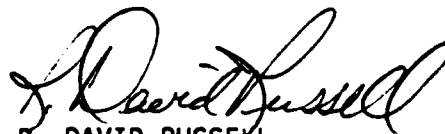
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TABLE. PRESENTATION OF DATA

| Test | Results | Interpretation |
|---|---|-------------------------------------|
| <u>SKIN IRRITATION STUDIES</u> | | |
| <u>Rabbits</u> | | |
| Single 24-hour application to intact and abraded skin of New Zealand White rabbits. | Chemical AI3-70957-Ga produced moderate to severe primary skin irritation of the intact skin and of the skin surrounding an abrasion. | USAEHA Category IV (ref Appendix A) |
| 0.5 mL technical grade chemical applied to each of six rabbits. | | |

5. CONCLUSION. Chemical AI3-70957-Ga produced moderate to severe primary irritation of intact skin and skin surrounding an abrasion. These studies were monitored by the Analytical Quality Assurance Office (see Appendix B).

6. RECOMMENDATION. Recommend that chemical AI3-70957-Ga be disapproved for further testing as a candidate insect repellent as described in the Toxicology Division Topical Hazard Evaluation Program Procedural Guide (reference paragraph 2, this report).

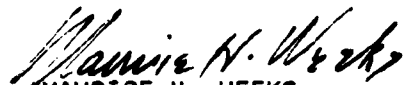


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CPT, VC

Laboratory Animal Veterinary Officer
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APPROVED:



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APPENDIX A

TOPICAL HAZARD EVALUATION PROGRAM
DEFINITIONS OF CATEGORIES OF COMPOUNDS BEING
CONSIDERED FOR ACUTE SKIN APPLICATION

CATEGORY I - Compounds producing no primary irritation of the intact skin or no greater than mild primary irritation of the skin surrounding an abrasion. (INTERPRETATION: No restriction for acute application to the human skin.)

CATEGORY II - Compounds producing mild primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should be used only on human skin found by examination to have no abrasions or may be used as a clothing impregnant.)

CATEGORY III - Compounds producing moderate primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should not be used directly on the skin without a prophetic patch test having been conducted on humans to determine irritation potential to human skin. May be used without patch testing, with extreme caution, as clothing impregnants. Compound should be resubmitted in the form and at the intended use concentration so that its irritation potential can be reexamined using other test techniques on animals.)

CATEGORY IV - Compounds producing moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion and, in addition, producing necrosis, vesiculation, and/or eschars. (INTERPRETATION: Should be resubmitted for testing in the form and at the intended use concentration. Upon resubmission, its irritation potential will be reexamined using other test techniques on animals, prior to possible prophetic patch testing in humans, at concentrations which have been shown not to produce primary irritation in animals.)

CATEGORY V - Compounds impossible to classify because of staining of the skin or other masking effects owing to physical properties of the compound. (INTERPRETATION: Not suitable for use on humans.)

APPENDIX B

ANALYTICAL QUALITY ASSURANCE

The Analytical Quality Assurance Office certifies the following:

a. These studies were conducted in accordance with:

(1) Standing Operating Procedures developed by the Toxicology Division, USAEHA.

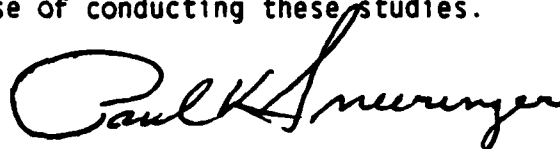
(2) Title 21, Code of Federal Regulations (CFR), 1983 rev, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

(3) Final Rule, Pesticide Programs; Good Laboratory Practice Standards; 48 Federal Register (FR) 53946-53969, 29 November 1983.

(4) Final Rule, Toxic Substances Control; Good Laboratory Practice Standards; 48 Federal Register (FR) 53922-53944, 29 November 1983.

b. Facilities were inspected during its operational phase to ensure compliance with paragraph a above.

c. The information presented in this report accurately reflects the raw data generated during the course of conducting these studies.



PAUL V. SNEERINGER, Ph.D.
Chief, Analytical Quality
Assurance Office

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